DEC 2 9 2005

Premarket Notification [510(k)] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K053308

Company: Horiba ABX
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4
FRANCE
Telephone: + (33) 4 67 14 73 20
Fax: + (33) 4 67 14 15 17

Contact Person: Tim Lawton (tlawton@fr.abx.fr)

Date Prepared: 22nd November 2005

Instrument :

Trade/Proprietary Name:	**ABX MICROS CRP 200**
Common or Usual Name:	Automated cell counter and Automated differential cell counter
Device Class	Class II : Special Controls Guidance Document
Classification Name:	Automated cell counter (§864.5200) and Automated differential cell counter (§864.5220)
Product Code:	GKZ : for the hematology analyzer

CRP Reagent

Trade/Proprietary Name:	**ABX CRP REA**
Common or Usual Name:	Conventional CRP Reagent
Device Class	Class II : Special Controls Guidance Document
Classification Name:	C-reactive protein immunological test system (§866.5270)
Product Code:	DCK : C-reactive protein, antigen, antiserum, and control

CRP Control

Trade/Proprietary Name:	**ABX CRP TROL I-III**
Common or Usual Name:	CRP Control
Device Class	Class I : exempt general conditions
Classification Name:	Quality Control Material (assayed & unassayed) (§862.1660)
Product Code:	JJX Single (specified) analyte controls (assayed and unassayed)

CRP Calibrator

Trade/Proprietary Name:	**ABX CRP STD**
Common or Usual Name:	CRP Calibrator
Device Class	Class II
Classification Name:	Quality Control Material (assayed & unassayed) (§862.1150)
Product Code:	JIS : Calibrator, primary

Optional device name :

Trade/Proprietary Name:	**iM (Information Management)**
Common or Usual Name:	Laboratory Information System
Device Class	Class I : exempt
Classification Name:	Calculator/data processing module for clinical use (§862.2100)
Product Code:	JQP

Substantial Equivalence:

The **ABX MICROS CRP 200** can be considered substantially equivalent to the predicate device **ABX MICROS CRP** cleared to market under K002646.

The fundamental scientific technology for the analyzer itself has not changed. All parameters for complete blood count, differential leucocyte count, the reagents and controls, measuring principles, and the principles of operation are the same as previously cleared by the FDA.

The dedicated CRP reagents used on the **ABX MICROS CRP 200** can be considered substantially equivalent to those previously used on the **ABX MICROS CRP.**

In addition, an optional add-on, to provide an Information Management System (iM) through which the ABX Micros CRP 200 ensures file management.

The overall effects on the Safety and Effectiveness of the Micros CRP 200 and the associated CRP reagents, controls and calibrators have been evaluated in internal & external clinical studies and internal validation procedures.

There is no known risk to the device Safety and Effectiveness.

Description:

ABX MICROS CRP 200 is an automated hematology analyzer that was developed by Horiba ABX (Montpellier, France). It utilizes cytochemistry, focused flow impedance, light scattering, and turbidity to provide quantitative information on complete blood cell and differential counts, in addition to other hematology parameters and conventional CRP.
CRP levels are measured in patients by reacting anti-CRP antibody coated latex particles with lysed blood, and determining the rate of the turbidimetric reaction in the near infrared spectrum.

Intended Use:

The **ABX MICROS CRP 200** is an open tube, automated (microprocessor controlled) hematology analyzer used for the *in vitro* diagnostic testing of whole blood & plasma specimens. The device operates in complete blood count (CBC) mode or in CBC & C-reactive protein (CRP) mode.
Measurement of conventional CRP aids in the evaluation of infection, tissue injury and therapy & monitoring of inflammatory disorders.

For the CRP mode, the MICROS CRP 200 uses dedicated HoribaABX reagents (ABX CRP REA), controls (ABX CRP TROL I & III) and calibrator (ABX CRP STD).

The MICROS CRP 200 may be coupled, on option, with an information management (iM) system.

Discussion of Performance Data:

The studies and data analysis were carried out in accordance with appropriate indications given by the FDA guidelines.

The data presented in this 510K Pre-market Notification demonstrate good precision in accordance with EP5-A (NCCLS guidelines) and is entirely acceptable for all available parameters.

The linearity claim for the parameters WBC (0 – 80 x $10^3/\mu L$), RBC (0 – 7.5 x $10^6/\mu L$), HGB (0 – 23g/dl), HCT (0 – 62.4%), PLT (0 – 900 x $10^3/\mu L$), conventional CRP for whole blood (0 – 200 mg/L), and plasma (0 – 150 mg/L) are entirely supported by the clinical data provided in this submission.

Accuracy (Inter-procedural Correlation) showed no evidence of significant bias between the ABX MICROS CRP 200 and the predicate devices.

The sample stability for leukocyte counts and the three part leukocyte differential is acceptable for over a 48 hour period from the time of blood collection at both room temperature and 4°C. For C-Reactive Protein determinations data assures there is sample stability over a 72 hour period at both room temperature and 4°C.

No effect of contamination of the instrument was dissimulated by the clinical data of this study, supporting a carryover claim of < 2.0% for WBC, RBC, HGB, PLT & CRP parameters.

Conclusions for non clinical and clinical tests :

The clinical studies tests conclude that the safety and effectiveness of the device is not compromised. Clinical testing met all acceptance criteria.

The device meets with the IEC 61010-1 standard of the International Electro-technical Commission on electrical equipment for measurement, control, and laboratory use. As well as the EN 61326 standard for Electromagnetic Compatibility.

All clinical and non clinical tests show appropriate levels of safety and effectiveness.

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K053308

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

   This change was for: 1. Providing a higher linearity limit for the CRP (C-Reactive Protein) parameter through the use of a new reagent and calibrator; 2. Adding an optional information management system.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and performance data such as precision, linearity, accuracy, sample stability, and carry-over.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Larry J. Brindza
(Reviewer's Signature)

12-27-05
(Date)

Comments

revised:3/27/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Tim Lawton
Regulatory Affairs Manager
Horiba ABX
Parc Euromèdecine
Rue du Caducèe-BP 7290
34184 Montpellier cedex 4
France

DEC 2 9 2005

Re: k053308
Trade/Device Name: ABX MICROS CRP 200 (option: iM)
ABX CRP REA
ABX CRP TOL I & III
ABX CRP STD
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ, DCK, JJX, JIS, JQP
Dated: November 22, 2005
Received: November 29, 2005

Dear Mr. Lawton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053308

Device Name: ABX MICROS CRP 200 (option : iM)

Indications For Use:

The **ABX MICROS CRP 200** is an open tube, automated (microprocessor controlled) hematology analyzer used for the *in vitro* diagnostic testing of whole blood & plasma specimens. The device operates in complete blood count (CBC) mode or in CBC & C-reactive protein (CRP) mode.
Measurement of conventional CRP aids in the evaluation of infection, tissue injury and therapy & monitoring of inflammatory disorders.

The MICROS CRP 200 may be coupled, on option, with a information management (iM) system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K053308

Indications for Use

510(k) Number (if known): K053308

Device Name: ABX CRP STD

Indications For Use:

The **ABX CRP STD** is intended to be used for the calibration of the **ABX CRP REA** reagent on the **ABX MICROS CRP 200** hematology analyzer for quantitative determination of C-reactive protein in human whole blood or plasma serum.

Measurement of conventional CRP aids in the evaluation of infection, tissue injury and therapy & monitoring of inflammatory disorders.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K053308

Indications for Use

510(k) Number (if known): K053308

Device Name: ABX CRP TROL I & III

Indications For Use:

The **ABX CRP TROL I & III** are intended to be used for the control of the **ABX CRP REA** reagent on the **ABX MICROS CRP 200** hematology analyzer for quantitative determination of C-reactive protein in human whole blood or plasma serum.

Measurement of conventional CRP aids in the evaluation of infection, tissue injury and therapy & monitoring of inflammatory disorders.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Division Sign-Off

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510(k) K053308

Indications for Use

510(k) Number (if known): K053308

Device Name: ABX CRP REA

Indications For Use:

The **ABX CRP REA** is a quantitative assay for use with the **ABX MICROS CRP 200** hematology analyzer for the determination of C-reactive protein in human whole blood or plasma serum.

Measurement of conventional CRP aids in the evaluation of infection, tissue injury and therapy & monitoring of inflammatory disorders.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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510(k) K053308